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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,109	07/01/2003	Richard C. Ewers	USGINZ02110	3376

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,109	EWERS ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12 and 46-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12 and 46-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 7-12, 55 and 57-60 are rejected under 35 U.S.C. 103(a) as being anticipated by Webler (U.S. Patent No. 6,955,657) in view of Hayhurst (U.S. Patent No. 6,656,182)

With respect to **claim 1:** Webler teaches a delivery catheter suitable for a gastric reduction system (Col. 2, lines 31,32), the delivery catheter comprising: an elongate torqueable and flexible tube 20 (Webler teaches that catheter 10 and 20 can be one structure) (Col. 2, line 39 - 43, Col. 3, line 57- Col. 4, line 2)); a needle 24/64 translatably disposed between a retracted position and a deployed position within the tube 20, with the needle 24/64 having a penetrating tip (Col. 7, lines 46-49, Col. 8, lines 56-60); and at least one anchor in the form of a release mechanism comprising an elastically deformable element that holds needle 24 in place during positioning of a needle and injection of a substance.

Webler does not explicitly teach an anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle 24. Hayhurst teaches a hollow needle having

a penetrating tip wherein an anchor is translatably disposed within said tip of said needle based upon Hayhurst's teaching that the member is pushed out of the device from the tip, and is moveable out of the penetrating tip of said needle when it is expelled therefrom once the apparatus is positioned at the tissue site. Hayhurst teaches that the device, including the anchor member positioned at said tip, solves the problem of manipulating and anchoring tissue when access to a tissue site is limited, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler so as to include an anchoring member that is placed within the tip of said needle 24 and is moveable out of the penetrating tip of said needle as taught by Hayhurst to facilitate manipulation and anchoring of tissue in sites where access is limited.

With respect to **claim 2:** The tube 10 taught by Webler is formed of a braided wire. ('657, Col. 4, lines 5-9)

With respect to **claim 7:** Webler teaches a coil 100 considered herein to be fixedly attached to a distal end of the tube 10, inasmuch as it prevents compression of the flexible body portion and prevents the collapse of outer braid 102 and could not do so without being fixedly attached. (Fig. 6, Col. 4, lines 5-9, 18-21)

With respect to **claim 8:** The coil, suggested by Webler as being formed from wire, thus necessarily includes a sharpened distal tip that is the tip of the wire. The limitation "to facilitate tissue penetration" constitutes functional language that is given little patentable weight herein.

With respect to **claim 9:** Webler teaches that the coil 100 comprises a multi-filar coil (i.e. a plurality of coils or coil elements) that form a central opening for the passage of the needle along the lumen of catheter 20 which is disposed in needle lumen 98 shown in Fig. 6. (Col. 3, lines 64,65, Col. 4, lines 9-11)

With respect to **claim 10:** As can be seen in Fig. 6, Webler teaches that the coil 100 and needle 24/64 (disposed within catheter 20 which is coaxial with lumen 98) are substantially coaxial.

With respect to **claim 12:** Hayhurst teaches a push rod 16 translatably disposed within the needle 14 and adapted to push the anchor 10 out of a distal end of the needle 14. The motivation to combine the devices of Webler and Hayhurst is stated *supra* with respect to claim 1. (182, Col. 4, lines 30-34, Col. 5, lines 11-14)

With respect to **claim 55:** Webler teaches a catheter comprising: an flexible and torqueable tube 10 having a front end and a back end; (Col. 2, line 39 - 43, Col. 3, line 57- Col. 4, line 2)); a needle 24/64 within said tube 10 (specifically within needle catheter 20 which is within tube 10) and having a piercing tip extendable out of the front end of the tube 10 via a release mechanism comprising spring 50 (Col. 7, lines 46-49, Col. 8, lines 56-60).

Webler does not explicitly teach one or more anchors stored within tube 10 and moveable out of the tube. Hayhurst teaches a hollow needle 14 within a tube 36 having a penetrating tip 26 wherein one or more anchors 10 is stored. Anchors 10 are translatably disposed within said tip 26 of said needle 14 based upon Hayhurst's teaching that the member is pushed out of the device from the tip 26, and is moveable out of the penetrating tip of said

needle when it is expelled therefrom once the apparatus is positioned at the tissue site. Hayhurst teaches that the device, including the anchor member positioned at said tip, solves the problem of manipulating and anchoring tissue when access to a tissue site is limited, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler so as to include an anchoring member that is placed within the tip of said needle 24 and is moveable out of the penetrating tip of said needle as taught by Hayhurst to facilitate manipulation and anchoring of tissue in sites where access is limited.

Webler also does not teach a suture. Hayhurst teaches suture 12 connected to anchor 10 and leading out towards the back end of tube 36. The motivation to combine the teachings of Webler and Hayhurst is stated *supra* in this rejection of claim 55.

With respect to **claim 57:** Webler teaches a coil 100 attached to a distal end of the tube 10. (Fig. 6, Col. 4, lines 5-9, 18-21)

With respect to **claim 58:** Hayhurst teaches a push rod 16 longitudinally moveable within the needle 14 for pushing an anchor 10 out of the tip of the needle 14. ('182, Col. 4, lines 30-34, Col. 5, lines 11-14) The motivation to combine the teachings of Webler and Hayhurst is stated *supra* in the rejection of claim 55.

With respect to **claim 59:** Webler teaches a catheter comprising: a flexible and torqueable tube 10 having a front end and a back end; a handle 25 attached adjacent to the back end of the tube 10 (Fig. 2, Col. 3, lines 57-59); a hollow needle 24/64 within the tube 10 and having a piercing tip extendible out of the front end of the tube 10 (Col. 7, lines 46-49, Col. 8, lines 56-

60). Webler teaches a needle control assembly on the needle catheter 20 and thus does not teach a needle control on the handle 25 linked to the needle, for moving the needle within the tube:

Webler does not explicitly teach one or more anchors stored within said needle 24 and moveable out of the needle tip during a surgical procedure. Hayhurst teaches a hollow needle 14 within a tube 36 having a penetrating tip 26 wherein one or more anchors 10 is stored. Anchors 10 are translatably disposed within said tip 26 of said needle 14 based upon Hayhurst's teaching that the member is pushed out of the device from the tip 26, and is moveable out of the penetrating tip of said needle when it is expelled therefrom once the apparatus is positioned at the tissue site. Hayhurst teaches that the device, including the anchor member positioned at said tip, solves the problem of manipulating and anchoring tissue when access to a tissue site is limited, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler so as to include an anchoring member that is placed within the tip of said needle 24 and is moveable out of the penetrating tip of said needle as taught by Hayhurst to facilitate manipulation and anchoring of tissue in sites where access is limited.

Webler also does not teach a suture. Hayhurst teaches suture 12 connected to one or more anchors 10 and with the suture 12 extending within tube 36 towards the back end of tube 36. The motivation to combine the teachings of Webler and Hayhurst is stated *supra* in this rejection of claim 59.

Webler does not teach an anchor ejector within the needle. Hayhurst teaches a push rod 16 longitudinally moveable within the needle 14 for pushing one or more anchors 10 out of the tip of the needle 14. ('182, Col. 4, lines 30-34, Col. 5, lines 11-14) The motivation to combine the teachings of Webler and Hayhurst is stated *supra* in this rejection of claim 59. Hayhurst teaches an anchor ejector control in the form of key 34 on the outside of the wall of the tube 16 linked to

the anchor ejector 16. The anchor ejector control key 34 is considered herein to be located on a handle, as the entirety of the outer cylindrical wall of rod 16 is considered herein as being configured to be a handle.

With respect to **claim 60:** Webler teaches a catheter comprising: an flexible tube 10 having a front end and a back end; (Col. 2, line 39 - 43, Col. 3, line 57- Col. 4, line 2)); a needle 24/64 within said tube 10 (specifically within needle catheter 20 which is within tube 10) and having a tip extendable out of the front end of the tube 10 via a release mechanism comprising spring 50 (Col. 7, lines 46-49, Col. 8, lines 56-60).

Webler does not explicitly teach one or more anchors stored within said needle 24 and moveable out of the needle tip during a surgical procedure. Hayhurst teaches a hollow needle 14 within a tube 36 having a penetrating tip 26 wherein one or more anchors 10 is stored. Anchors 10 are translatably disposed within said tip 26 of said needle 14 based upon Hayhurst's teaching that the member is pushed out of the device from the tip 26, and is moveable out of the penetrating tip of said needle when it is expelled therefrom once the apparatus is positioned at the tissue site. Hayhurst teaches that the device, including the anchor member positioned at said tip, solves the problem of manipulating and anchoring tissue when access to a tissue site is limited, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler so as to include an anchoring member that is placed within the tip of said needle 24 and is moveable out of the penetrating tip of said needle as taught by Hayhurst to facilitate manipulation and anchoring of tissue in sites where access is limited.

Webler also does not teach a suture. Hayhurst teaches suture 12 connected to one or more anchors 10 and with the suture 12 extending within tube 36 towards the back end of tube

36. The motivation to combine the teachings of Webler and Hayhurst is stated *supra* in this rejection of claim 60.

Claims 3-5, 48 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webler (U.S. Patent No. 6,955,657) in view of Hayhurst (U.S. Patent No. 6,656,182) as applied to claims 1, 2, 7-12, 55 and 57-60 above, and further in view of O'Keefe (U.S. Patent No. 6,921,378).

With respect to **claim 3:** Neither Webler nor Hayhurst teaches a tube that contains a plurality of larger cut slots disposed substantially perpendicular to a longitudinal axis of the tube. O'Keefe teaches a drainage catheter having slots present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Webler and Hayhurst so as to have a plurality of larger cut slots as taught by O'Keefe to aid liquid flow through the retention end of said tube.

With respect to **claim 4:** O'Keefe does not explicitly teach that the slots are formed in a sinusoidal pattern. However O'Keefe teaches that "the slots may be straight, curved or helical along the wall and have a polygonal or curved cross-section" Since O'Keefe teaches curved slots, of which sinusoidal slots is an example, it would be obvious to one of ordinary skill in the art to modify the slots of the combined teaching of Webler and Hayhurst and O'Keefe so as to

have sinusoidal slots with a reasonable expectation of success to allow the flow of liquid through the segment of a catheter containing such sinusoidal slots. The motivation to combine the teachings of Webler and Hayhurst and O'Keefe is stated *supra* with respect to claim 3.

With respect to **claim 5:** O'Keefe teaches a drainage catheter having slots present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases. The motivation to combine the teachings of Webler and Hayhurst and O'Keefe is stated *supra* with respect to claim 3.

With respect to **claim 48:** Neither Webler nor Hayhurst teaches a tube that contains a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube.

O'Keefe teaches a drainage catheter having a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube and present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) Therefore placing slots in delivery catheter 520 at a distal end would be obvious to one of ordinary skill in the art as the catheter 520 performs a substantially identical function to that taught by O'Keefe.

The limitation "to increase the flexibility of the tube" constitutes functional language that is given little patentable weight herein.

With respect to **claim 56:** Neither Webler nor Hayhurst teaches a tube that contains a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube.

O'Keefe teaches a drainage catheter having a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube and present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) Therefore placing slots in delivery catheter 520 at a distal end would be obvious to one of ordinary skill in the art as the catheter 520 performs a substantially identical function to that taught by O'Keefe.

The limitation "to increase the flexibility of the tube" constitutes functional language that is given little patentable weight herein.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webler (U.S. Patent No. 6,955,657) in view of Hayhurst (U.S. Patent No. 6,656,182) as applied to claims 1, 2, 7-12, 55 and 57-60 above, and further in view of Martin et al (U.S. Patent Application Publication No. 2003/0167071).

With respect to **claim 11:** Webler does not teach that the coil 100 is not translatably disposed within a delivery catheter lumen 98. Hayhurst also does not teach a coil translatably disposed within a delivery catheter lumen 98. Martin teaches that coil element 102 is a positioning device for sutures positioned therethrough and is slidable to a desired position along catheter 200. ('071, ¶¶ 0056,0057) Martin also teaches that such sliding allows said coil element 102 to be advanced along a suture to a desired position for anchoring or fastening, therefor eit would be obvious to one of ordinary skill in the art to modify the device of Webler and Hayhurst so as to have a coil translatably disposed within a tube lumen to aid or replace the suture anchor taught

by Hayhurst and further allowing proper positioning and fastening of the sutures at a desired site as taught by Martin.

Claims 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (U.S. Patent No. 6,656,182) in view of Webler (U.S. Patent No. 6,955,657).

With respect to **claim 46:** Hayhurst teaches a catheter comprising: a tube in the form of cylindrical member 36 with open ends having a front end and a back end (Fig. 2, Col. 5, lines 47-49); a needle 14 within the tube 36 and having a tip 26 extendible out of the front end of the tube (Fig. 2, Col. 4, lines 66,67, Col. 5, lines 47-49); at least one anchor 10 positioned within the flexible tube (specifically within needle 14 which is within tube 36) and moveable out of the flexible tube 36 by movement out of needle 14 during a surgical procedure (Col. 4, lines 30-33) ; and a suture 12 connected to one or more of the anchors 10, and with the suture 12 extending within the tube 36 towards the back end of the tube 36, wherein the back end is the end distal to the needle tip. (Fig. 2, Col. 4, lines 47-50)

Hayhurst does not teach that said tube is flexible. Weblet teaches a needle 24 within a flexible tube 10. Webler teaches that the flexibility allows for easier placement of said needle catheter 20, therefore it would be obvious to one of ordinary skill in the art to modify the article of Hayhurst so as to replace the tube 36 with a flexible tube as taught by Webler to allow ease of access and placement of said needle and needle catheter.

With respect to **claim 47:** Hayhurst does not teach that the tube 36 is torqueable or that said tube is formed of braided wire. Webler teaches a catheter 10 having a tube that is torqueable and formed of braided wire 102. (Col. 2, lines 39-44, Col. 4, lines 3-9) Webler teaches that the braided wire 102 provides maximum torque response when the instant tube 10 is rotated, therefore it would be obvious to one of ordinary skill in the art to modify the device of Hayhurst so as to be formed of braided wire as taught by Webler to maximize torque response when the tube is rotated.

With respect to **claim 49:** Weber teaches that catheter 10 comprises a coil 100 at the front end of the flexible tube, with the coil having a sharp tip.

With respect to **claim 50:** Hayhurst teaches that needle 14 having a penetrating tip 26 is adjacent to the front end of the flexible tube 36. (Fig. 2)

With respect to **claim 51:** Hayhurst teaches in Fig. 2 a needle 14 positioned to extend out of the front end of the flexible tube 36.

Hayhurst does not teach a coil and thus does not teach that needle 14 is positioned in Fig. 2 to extend through a coil. Webler teaches a needle with a retracted position in which said needle is positioned to extend out of the front end of the flexible tube at a subsequent time and through coil 100. The motivation to combine the devices of Hayhurst and Webler is stated *supra* with respect to claim 46.

With respect to **claim 52:** Hayhurst teaches a push rod 16 longitudinally moveable within the needle 14 for pushing one or more anchors 10 out of the tip of the needle 14. ('182, Col. 4, lines 30-34, Col. 5, lines 11-14)

With respect to **claim 53:** The needle 14 taught by Hayhurst is considered herein to have a non-coring tip. Although the tip is hollow, has a lumen and is sharp and is thus technically capable of coring, Hayhurst does not teach using the tip to core, thus the tip is considered herein to be taught by Hayhurst to be a non-coring tip.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (U.S. Patent No. 6,656,182) in view of Webler (U.S. Patent No. 6,955,657) as applied to claims 46-53 above, and further in view of Iwami et al (U.S. Patent Application Publication No. 2002/0087098).

With respect to **claim 54:** Hayhurst does not teach a tube with a coating of fluorine resins. Webler teaches that the tube 10 has a plastic coating 104 but does not teach a coating of fluorine resins. Iwami teaches coating a catheter with fluorine resin to act as a location marker for observation of the progress of the tube during endoscopy while the tube is in the body. Therefore, since Webler teaches a similar mark, or location sensor, for the same purpose, it would be obvious to one of ordinary skill in the art to modify the device of Hayhurst and Webler so as to have a tube with a coating of fluorine resin as taught by Iwami to provide a mark on the tube to allow observation of the tube's progress during an endoscopy. ('098, ¶¶0026,0034,0035,0102)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

August 15, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER